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A development of a technique for measuring the compliance of the textile vascular prostheses

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Abstract

The objective of this study is to develop a technique for measuring the compliance of the textile vascular prostheses without membrane. The principle of this test is to investigate the dimensional changes of prostheses, using imaging techniques, submitted to internal pressure. The internal compliance is broken into three categories: the radial compliance, the longitudinal compliance and the volumetric compliance. The results have shown a significant difference in compliance between the polyethylene terephthalate (PET) vascular grafts and the healthy host arteries.

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Keywords: vascular prostheses; PET; compliance; viscous liquid; imaging techniques; wall thickness; crimping geometry.

1. Introduction

The establishment of criteria and ideal requirements which the arterial grafts have to meet, remains an important issue for suppliers, surgeons and patients [1-3]. The major problem resides in the identifying of reliable tests for judging the efficiency of those alternatives. However, during the development of such a test, experimental conditions, laws of behavior and the environment of prostheses in the human body should be imperatively considered.

The challenge for producing vascular grafts is to engineer vascular replacements that can withstand pulsation and are able to withstand the high pressure and flow rate of the blood stream. Compliance matching also presents a major challenge and has been addresses by modifying the materials, structure, and fabrication of the graft [3], without compromising the capacity for cells to form strong attachments and a complete monolayer covering of the graft to reduce thrombus [4]. Mismatch in the elastic or compliance properties of prosthetic graft and adjacent native

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artery have been implicated in the aetiology of distal anastomotic myointimal hyperplasia, a major cause of prosthetic graft failure [5,6]. In addition, compliance mismatch produces flow disturbance and increases mechanical stress near anastomotic sites in flow models [7,8]. For this, the graft should have high transverse compliance, be able to recover fully and rapidly from the change in diameter after each pulsation cycle of blood, and the desired, i.e. predictable, porosity.

The objective of this study is to develop a technique for measuring the compliance of arterial prostheses without membrane. Various characterization tests were conducted to determine aspects of textile prostheses tested.

2. Materials and Methods

Vascular grafts used in this work are collagen-coated knitted structures with different wall thickness values and crimping geometry. These prostheses; made of polyethylene terephthalate (PET); have a nominal diameter of about 8-9 mm and a length of 10 cm (Fig. 1).

The prostheses thickness has been evaluated by using compression and thickness devices of Kawabata system. Coating of prosthesis was removed before testing. This test was achieved in accordance with the standard ISO 7189 “Cardiovascular implants-Tubular vascular prostheses” [9].

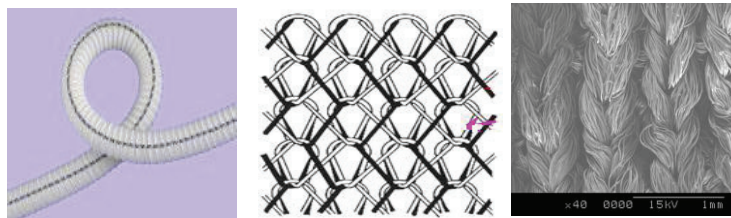


Fig. 1: Warp knitted structure and SEM micrograph of prostheses

The hydrostatic device developed (Fig. 2) is composed of a compressor, a fluid reservoir, a compliance tank in which the sample is fixed and a pressure sensor located at first end of the sample. The value of the pressure of viscous liquid ejected within the sample will be displayed continuously. The tubular graft sample is cannulated at both ends. One end is connected to a fixed support to which a pressure bottle containing fluid is attached. The second end is closed by an obturator centered on a metal rod allowing free graft elongation during pressurization. The tests are conducted while the sample is immersed in a physiological solution maintained at ambient temperature.

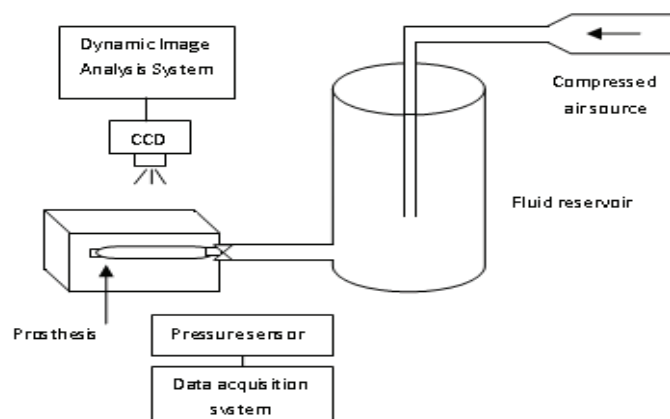


Fig. 2: The schematic of the hydrostatic pressure-strain experimental device.

The prosthesis is subjected to various pressure (from 0 to 240 mmHg) corresponding to the physiological pressure exerted on the artery wall during the cardiac cycle. With the help of image analysis, the changes in the dimensions of prosthesis are investigated. For each mean pressure, two pictures were taken with a video camera. These pictures were scanned and processed by Image J V.1.43n (NIH Image) software. A small program was written to process the images in the same way (Fig. 3). This program identifies the prosthesis outer contour which allow, using Microsoft–Excel, to locate any given point by its coordinates. This helps in determination dimensions and deformations of prostheses such as the mean external diameter, the longitudinal elongation and the volume change.

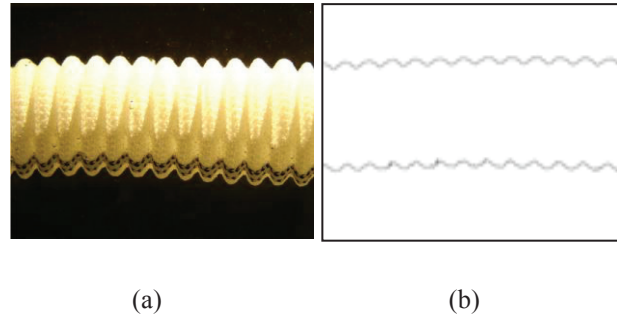


Fig. 3: Image analysis: (a) picture of the graft during the test and (b) treated image.

Compliance is a measure of the capacity of distension of a structure under physiological blood pressure. It also represents an index that is associated with the graft's capability of increasing in volume under a given internal pressure [10]. This property is analogous to elasticity in the colloquial sense of the word. Thus, arterial compliance varies continuously depending on the intravascular pressure. The volumetric compliance (CV) is expressed as the ratio of the change in volume (ΔV) of the arterial graft and the change in pressure (ΔP) of liquid or air ejected [11]. The expression is as follows:

$$C_V = \Delta V \text{ (mm}^3\text{)} / \Delta P \text{ (mm Hg)} \quad (3)$$

There are two others possible ways of defining compliance: the longitudinal compliance (CL) and radial compliance (CR) which can be calculated as follows:

$$C_L = \Delta L \text{ (mm)} / \Delta P \text{ (mm)} \quad (4)$$

$$C_R = \Delta R \text{ (mm)} / \Delta P \text{ (mm)} \quad (5)$$

where ΔL and ΔR are change in length and change in radius respectively.

3. Results and discussion

3.1. Characteristics of prostheses

A summary of the wall thickness and the crimping geometry for prostheses is provided in Table 1. The prosthesis P1 has the finest textile wall which makes it more flexible. This prosthesis has better maneuverability and conformability as compared to other prostheses. The prosthesis P3 has a different crimping from that of prostheses P1 and P2.

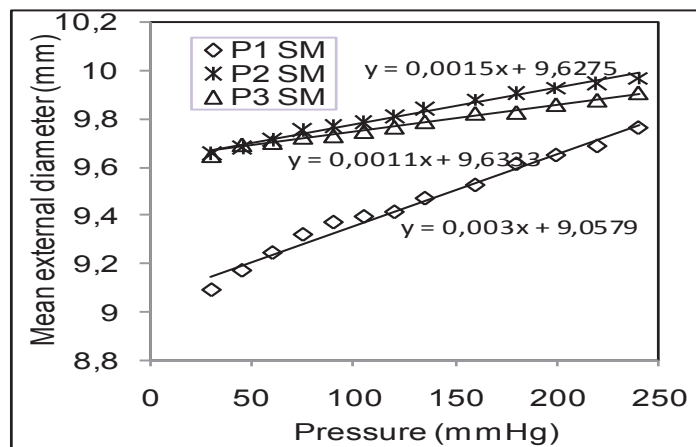
Table 1: Characteristics of prostheses

Prosthesis	P1	P2	P3
Wall thickness (mm)	0.32	0.7	0.9
Crimping geometry	helical	helical	circular

3.2. Compliance study

The compliance testing is carried out on three different prostheses. Each sample had a nominal diameter of about 8-9 mm and a length of 10 cm. Previous studies [12,13] have shown that tests for measuring compliance properties were carried out on prostheses with membranes. Due to the permeability of textile vascular grafts at high pressure (>100mmHg), a highly deformable membrane may be introduced in each sample. But this membrane creates links with the inner surface of the crimps and considerably modified the graft behavior when submitted to internal pressure. In order to counteract these limitations, we developed a modified hydrostatic pressure-strain device. The tests are conducted while the sample without membrane is immersed in a physiological high viscosity solution maintained at ambient temperature. This method simulates more directly the in vivo conditions and will be the preferred approach for evaluating the performance of a product in the final stages of its development.

Figure 4 depicts the evolution of external diameter of prostheses versus the pressure. It is clear that the prosthesis P1 is more compliant in diameter, whereas the prosthesis P3 is the least compliant. The mean external diameter of the prosthesis P1 experiences an increase of 0.7 mm for an internal pressure between 30 and 240 mmHg. This may be explained by its low wall thickness which makes this prosthesis more deformable and less resistant to the high pressure and flow rate of the blood stream [14]. Despite a significant increase in the diameter of prosthesis P1, it remains less compliant in comparison with healthy artery of the host which varies from 6.3 to 7.1 mm for a pressure of 30-100 mmHg [15].

**Fig. 4:** Evolution of the mean external diameter of prostheses.

The pressurization of the prosthesis engenders a fast elongation in the beginning of the test (Fig. 5). Then the elongation is less dramatic with an increase in internal pressure. It is also demonstrated that the prosthesis P3 stretches more than the other grafts as a result of the pressure wave. It should be noted that the prosthesis P3 has a circular crimping but P1 and P2 have a helical crimping. This fact reveals that the crimping geometry affects the elongation of prostheses during the compliance testing.

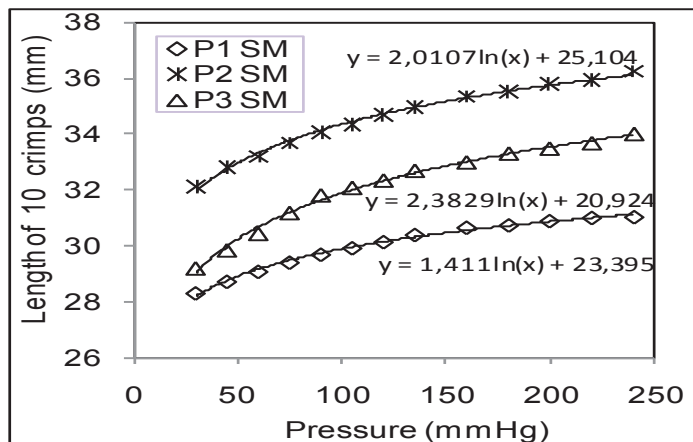


Fig. 5: Evolution of the elongation of prostheses.

The tests for measuring volumetric compliance showed a slight difference between the three prostheses. Figure 6 represents the evolution of the volume of prostheses versus the fluid pressure. It was demonstrated that prosthesis P1 was slightly more compliant than the other two prostheses. Referring to figures 4 and 5, the prosthesis P1 has more swelling effect than elongation. Therefore, it is important that three different kinds of compliance have been determined separately. So, the effects of construction and processing factors on properties of prostheses are not linear or simple to predict [16].

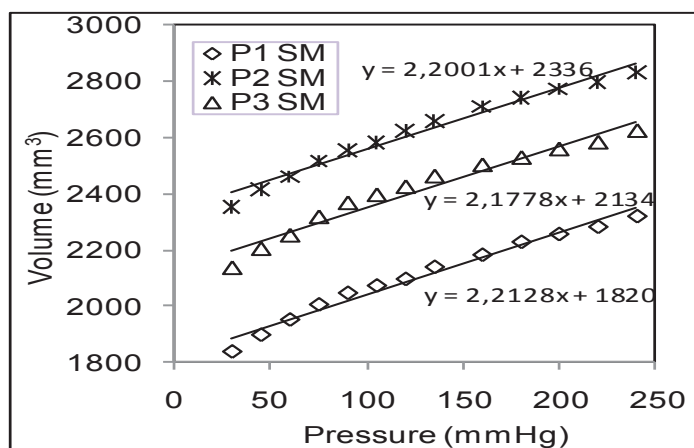


Fig. 6: Evolution of the volume of prostheses

4. Conclusion

In summary, the technique of compliance measurements using hydrostatic force method on vascular grafts without membrane provides a valuable tool to differentiate the three categories of compliance. Results have shown a significant difference in compliance between these vascular prostheses and the healthy host arteries. These results confirm that the compliance properties of textile vascular grafts are affected by many factors such as wall thickness and crimping geometry.

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